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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,194	04/23/2001	Timothy P. Croughan	98A9-USCROUG	2938

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EXAMINER
KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/830,194	CROUGHAN, TIMOTHY P.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,31,38,54,61 and 129-185* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,31,38,54,61 and 129-185* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 and 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-15, 31, 38, 54 and 61 in Paper No. 12, filed 2 January 2003, is acknowledged. New claims 129-185 have been added and are directed to the elected invention and will be examined with the elected invention.

2. Claims 32-37, 55-60 and 82-128 have been cancelled as requested in the response filed 2 January 2003.

3. The Examiner confirms Applicant's assertion on page 3, 5th paragraph, of the Response that claims 1-15, 31, 38, 54, 61 and 129-185 are pending the in the instant application.

4. The Examiner notes that claim 30 was not listed in the Annexes that were entered in the correction entered 31 October 2002 in Paper No. 9. The Examiner has indicated on the file wrapper that claim 30 is no longer pending.

Information Disclosure Statement

5. The information disclosure statements filed 20 July 2001 and 17 September 2001 have been considered, a copy of each is attached hereto.

6. On the IDS filed 17 September 2001, the reference to pending application 09/934,973 has been considered but will not be published on the face of the patent under the section "References Cited".

Specification

7. The disclosure is objected to because of the following informalities: At page 11, line 12, the ATCC Accession Nos. "aaaaa", for example, do not denote actual accession number. Applicant is advised to avoid new matter issues when responding to this Office action.

Appropriate correction is required.

Claim Objections

8. Claims 2-15, 31, 38, 54, 61 and 129-185 are objected to because of the following informalities:

At claims 2-31, the phrase "A rice plant" should read -- The rice plant -- in referring to the rice plant of claim 1.

At claims 38, 61 and 180, line 1, the phrase "a rice plant" should read -- the rice plant -- in referring to the rice plant of claim 1.

At claim 54 and 143-156, the phrase "A process" should read -- The process -- in referring to the process of claim 38.

At claims 129-142, the phrase "A rice plant" should read -- The rice plant -- in referring to the rice plant of claim 31.

At claims 157-170, the phrase "A process" should read -- The process -- in referring to the process of claim 54.

At claims 171 and 176-178, the phrase "A process" should read -- The process -- in referring to the process of claim 61.

At claims 172-175, the phrase "A process" should read -- The process -- in referring to the process of claim 171.

At claims 181 and 182, the phrase "A process" should read -- The process -- in referring to the process of claim 180.

At claim 183, line 1, the phrase "a rice plant" should read -- the rice plant -- in referring to the rice plant of claim 31.

At claims 184 and 185, the phrase "A process" should read -- The process -- in referring to the process of claim 183.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-15, 31, 38, 54, 61 and 129-185 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 1(b), line 1, the phrase "is a derivative of the plant" is indefinite because there are many ways to derive a rice plant, hence it is unclear what the metes and bounds of the claim are.

At claims 1, 31, 54 and 171, the phrase "ATCC accession number PTA-904" is indefinite because the specification does not teach "ATCC accession number PTA-904", hence it is unclear what the metes and bounds of the claims are.

Claims 2-15, 31, 38, 54, 61 and 129-185 are also deemed to be indefinite because they are all ultimately dependent upon claim 1 and do not obviate the indefiniteness of claim 1.

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-15, 31, 38, 54, 61 and 129-185 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a herbicide-resistant rice plant that is resistant to inhibition by at least one AHAS inhibiting herbicide, is a "derivative" of the rice plant with ATCC accession number PTA-904 and has the herbicide resistance characteristics of the plant with ATCC accession number PTA-904.

Applicant describes herbicide-resistant rice plants produced by EMS mutagenesis with resistance to herbicides that inhibit the function of a non-mutant AHAS enzyme (pages 8-13 of the specification). Applicant also describes specific herbicide-resistant rice plants produced having been deposited with the ATCC (see pages 9 and 11 of the specification).

Applicant does not describe what specific mutations have occurred in the exemplified herbicide-resistant rice plants or how to distinguish the exemplified

herbicide-rice plants or progeny thereof from other herbicide-resistant rice plants that are mutant. In addition, it is unclear if Applicant has specifically described the rice plant with ATCC accession number PTA-904 in the instant specification because there is no reference to such an accession number therein.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *Brenner v. Manson*, 383 U.S. 519 (1966), which states "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. In the instant case, Applicant does not describe the structure of the invention by which one of skill in the art could recognize Applicant's claimed invention, other than the function of the herbicide-resistant rice plant. In addition, Applicant admits that Applicant does not understand the resistance mechanism the produces the function within the deposited PTA-904 herbicide-resistant rice plant (see page 7, 2nd paragraph of the specification).

13. Claims 1-15, 31, 38, 54, 61 and 129-185 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the herbicide resistant rice plant 'PWC16' (apparently deposited as ATCC Accession Number PTO-904) and methods of using same, does not reasonably provide enablement for any "derivative" or progeny of said deposited rice plant, any rice plant having the herbicide resistance characteristics of the plant 'PWC16' (apparently deposited as ATCC Accession Number PTO-904) or methods of using such "derivative" or progeny rice plants. The Croughan Affidavit filed 2 January 2003, as Paper No. 11, suggests that rice plant PTA-904 is variety 'PWC16', in view of Table 1 on page 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a herbicide-resistant rice plant that is resistant to inhibition by at least one AHAS inhibiting herbicide, is a "derivative" of the rice plant with ATCC accession number PTA-904 and has the herbicide resistance characteristics of the rice plant with ATCC accession number PTA-904.

Applicant teaches a method of isolating herbicide-resistant rice plants produced by EMS mutagenesis with resistance to herbicides that inhibit the function of a non-mutant AHAS enzyme (pages 8-13 of the specification). Applicant also teaches specific herbicide-resistant rice plants produced by said method having been deposited with the ATCC (see pages 9 and 11 of the specification).

Applicant does not teach what specific mutations have occurred in the exemplified herbicide-resistant rice plants or how to distinguish the exemplified

herbicide-rice plants or progeny thereof from other herbicide-resistant rice plants that are mutant. In addition, it is unclear if Applicant has specifically teaches the rice plant with ATCC accession number PTA-904 in the instant specification because there is no reference to such an accession number therein.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant teaches specific mutant rice plants that have resistance to herbicides that inhibit plant AHAS enzymes (see pages 9 and 11). Applicant does not teach what these mutations are in the exemplified herbicide-resistant rice plants. Applicant only teaches the phenotype of the exemplified herbicide-resistant rice plants. Applicant admits that the resistance mechanism of the rice lines has not been fully characterized (see page 7, 3rd paragraph). Given the nature of the invention and the lack of direction or guidance given in the instant specification as to the actual nature of the herbicide resistance characteristics of the plant 'PWC16' (apparently deposited as ATCC Accession Number PTO-904), other than it appears to be associated with a mutated AHAS enzyme-encoding gene, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to determine

all of the characteristics of the rice plant 'PWC16' (apparently deposited as ATCC Accession Number PTO-904) that are associated with the herbicide resistance characteristics by which one of skill in the art could recognize a "derivative" of the plant 'PWC16' (apparently deposited as ATCC Accession Number PTO-904).

In addition, the claims are not fully enabled because the claimed rice plant at claim 1 can be read to encompass a rice plant that is a "derivative" of ATCC accession number PTA-904, but the "herbicide resistance characteristics of the plant with ATCC accession number PTA-904" can be introduced from another rice plant. Since Applicant only teaches one of skill in the art that the "herbicide resistance characteristics" of the deposited plant appears to be an AHAS mutation, one of skill in the art would have required undue trial and error experimentation to duplicate the "herbicide resistance characteristics" in another rice plant and produce the claimed "derivative" rice plant.

Also, claims 1, 6, 38, 133, 147 and 161 are directed to a rice plant that is resistant to sulfoneturon methyl. In the specification on page 17, Table 2, Applicant appears to indicate that variety 'PWC16' (apparently deposited as ATCC Accession Number PTO-904) is not resistant to sulometuron methyl, hence, the claims do not appear to be enable to the extent that they read on a rice plant having such resistance. There also appears to be no resistance to chlorimuron ethyl or rimsulfuron and little resistance to nicosulfuron at Table 4 on page 24 of the specification.

14. Claims 1-15, 31, 38, 54, 61 and 129-185 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant(s) is(are) essential to the claimed invention it(they) must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It appears that applicants have deposited the plant(s) but there is no indication in the specification of this fact or that all of the requirements have been met (see below).

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a

statement by an attorney of record over his or her signature and registration number, showing that

(i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,

(v) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102/103

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 1-15, 31, 38, 54, 61 and 129-185 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275).

The indefiniteness of the term "derivative" plant is outlined above.

Terakawa *et al* disclose a herbicide-resistant rice plant wherein growth of said rice plant is resistant to at least one herbicide that normally inhibits AHAS enzymes (syn. ALS used by Terakawa *et al*), is a derivative of a rice plant obtained by exposing rice plants to mutation-inducing conditions, expresses a functional AHAS enzyme that is resistant to inhibition by at least one herbicide that normally inhibits AHAS enzymes (see Table 4 on page 271). Terakawa *et al* disclose that said rice plant is resistant to at least one sulfonylurea herbicide. It was know in the art at the time of Applicant's invention that mutations in the AHAS enzyme give rise to resistance to sulfonylurea and/or imidazolinone herbicides, thus without evidence to the contrary, the rice plant of Terakawa *et al* would inherently be resistant to at least one imidazolinone herbicide also, including those listed in the dependent claims of the instant application. Terakawa *et al* disclose a process for controlling weeds in the vicinity of the disclosed rice plant comprising applying a herbicide to the weeds and to the rice plant (page 269).

Terakawa *et al* is silent as to the full spectrum of sulfonylurea and imidazolinone herbicides the disclosed plant is resistant to, and to the exact nature of the resistance of the AHAS enzyme, *i.e.* any amino acid substitutions.

Because the claimed "derivative" plant is unclear as outlined above, and the progeny could be the result of an infinite number of crosses, merely selecting for the herbicide resistance characteristics of PTA-904, and because Applicant has not characterized what the actual resistance mechanism is, *i.e.* specific mutation in the rice AHAS enzyme, the herbicide resistant rice plant of Terakawa *et al* or herbicide resistant progeny thereof would be anticipated and indistinguishable from the claimed herbicide resistant rice plant, simply based on the characteristics of the herbicide resistance.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-15, 31, 38, 54, 61 and 129-185 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,773,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because;

The claims of the issued Patent teach a herbicide-resistant rice plant that has the herbicide resistance characteristics of the plant deposited with ATCC accession number

97523. The issued claims to not limit the number of generations away from said deposited plant.

The herbicide-resistant rice plant of the instant claims is obvious over the herbicide-resistant plant of the issued patent, because one of ordinary skill in the art would not be able to distinguish the "derivative" plant of the patented herbicide-resistant rice plant from the "derivative" plant of ATCC accession number PTS-904 of the instant claims. In addition, neither the issued patent nor the instant application teaches what the actual herbicide resistance mechanism is, *i.e.* the mutation in the AHAS protein, by which one of ordinary skill in the art could distinguish "derivative" or "progeny" of either herbicide-resistant rice plant.

20. Claims 1-15, 31, 38, 54, 61 and 129-185 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62, 64, 66, 68 and 70 of copending Application No. 09/934,973. Although the conflicting claims are not identical, they are not patentably distinct from each other because;

Copending Application No. 09/934,973 claims a herbicide-resistant rice plant that expresses a functional AHAS enzyme that is resistant to inhibition by at least one herbicide that normally inhibits AHAS. The instant claims are *prima facie* obvious in view of copending Application No. 09/934,973 because the instant claims are directed to "derivative" rice plants and "progeny" rice plants, rice plants of which the nature of the herbicide-resistance is not taught.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

David H. Kruse, Ph.D.
6 March 2003